REMARKS

Reconsideration of this application is requested.

The indicated allowance of claim 12 on Office Action summary page is noted. However, it also noted that claim 12 is included with other claims rejected under Section 112 on page 3 of the action. Clarification is requested.

The withdrawal of the art rejection is also noted.

The Examiner is requested to reconsider the Section 112, 1st ¶ rejection of claims 13, 15-22 and 24-31 in view of the amendments to the claims as highlighted in the Appendix.

More specifically, reference to "nutritionally" has been canceled from the claims. While the applicants do not agree with the Examiner's objection to the term "nutritionally active", it is evident that the term "nutritionally" is unnecessary for proper definition of the invention. The Examiner has recognized that the applicants' specification provides support for oleanoic acid, ursolic acid, policosanol and phytosterols to be "active ingredients" (page 2, 2nd ¶, 2nd sentence of the action). In the circumstances, the further qualifying reference to these materials as "nutritionally" active is redundant and otherwise unnecessary.

It is noted that the Examiner responded to the applicants' reliance on claim 24 and page 3, lines 6-10 as justifying the previous claim references to "nutritionally active organic solid component", by stating that claim 24 is not an original claim and that page 3, lines 6-10 "defines the active component and not the nutritionally active component'. For the sake of completeness, the applicants point out that original claims 6 and 7, which became claims 23 and 24, specifically referred to the active organic solid component as a "nutritionally active" component. Thus, there is clear and enabling description in the

applicants' original filing justifying the reference to "nutritionally active" in the claims. However, this is a moot point in view of the indicated amendments to the claims and the acknowledgement by the Examiner that the applicants' disclosure is enabling for use of "an active component".

Reconsideration of the Section 112, 2nd ¶ rejection of claims 12-31 as indefinite for the reasons set out in the first two ¶s, page 3 of the action is requested. The applicants submit that the language of their claims is clear and definite. The Examiner states that it is "not seen that any and all active ingredients are effective in producing the desired improved organoleptic flavor in a product". According to the Examiner, only the particular ingredients set forth at page 1, lines 6-7 are seen as the active organic components. However, it is respectfully submitted that the disclosure of specific materials at page 1, lines 6-7, as representative examples of food additives, does not make the applicants' claim language indefinite. The Examiner's comments seem to go more to the scope of the claims, not to any uncertainty or indefiniteness in the claimed language. Furthermore, it is clear from a reading of the applicants' disclosure that the invention is not limited to the particular additives or ingredients referred to at page 1, lines 6-7. The invention as disclosed clearly relates broadly to the case where solid organic active components are added to foods where the additive might otherwise cause problems in mouthfeel or bio-availability or homogeneity of the food product. See, for example, the 1st and 2nd ¶s, page 1 of the applicants' specification. Clearly, the applicants' invention applies to any active solid organic food additive where the indicated problems have arisen in the past and those in the art would have no difficulty in determining the metes and bounds of the claimed invention from the current claim language. In brief, the applicants' invention is not dependent on the use of specific food

additives; it is broadly useful to deal with the indicated prior art problems. The claim language is clear and should be acceptable.

As further evidence of the wide application of the invention, there are attached hereto examples illustrating the use of the invention with ursolic acid and soy protein. Thus, the invention is clearly not limited in its application to the specific representative examples given in the disclosure and the claims should not be limited thereto.

Notwithstanding the foregoing comments, the claims have been amended to call for the active component to be an active solid organic "food additive". This more specifically defines the additive consistent with the applicants' disclosure and should be acceptable to the Examiner, particularly since it is evident from the applicants' disclosure that the invention is concerned with the addition of such components to foods. See, for example, page 1 of the applicants' specification. There is, therefore, clear support for the amended claim language.

Reconsideration of the Section 112, 1st ¶ rejection of claims 12-31 as enabled only for the ingredients set out at page 1, lines 6-7, is requested. The applicants' claims are fully enabled as presented for reasons evident from the foregoing comments. The disclosure provides representative examples of additives for use according to the invention. However, those in the art will recognize that the disclosure is more broadly enabling consistent with the scope of the claims. The use of, for example, soy protein as shown by the attached examples, is an illustration of this. The Examiner has given no reason at all why one in the art could not practice the invention over the scope claimed. In the absence of some technical difficulty as to why the invention is not enabled for one in the art, the claims must be accepted as fully enabled.

Finally, the applicants wish to call the Examiner's attention to U.S. Patent 6,436,453, copy attached, recently cited against related application Serial No. 09/816,863. The patent does not disclose the applicants' invention, for example, the claimed network matrix structure incorporating the active additive. However, the applicants wish to have the reference made of record for the Examiner's consideration. A PTO-1449 listing the patent is attached.

Favorable reconsideration of the application is requested.

Respectfully submitted,

MORGAN LEWIS & BOCKIUS LLP

By _____
Paul N. Kokulis
Reg. No. 16773

PNK:mh
1111 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
Phone: (202) 739-3000
Facsimile: (202) 739-3001
Direct: (202) 739-5455

APPENDIX
Version with Markings to Show Changes Made

IN THE CLAIMS

The claims are amended as follows:

12. (Twice Amended) A structured particulate system comprising at least one [nutritionally] active, organic solid [component] food additive incorporated in a matrix which forms a network completely incorporating said [nutritionally] active, organic solid [component] food additive in a weight ratio of 1:99 of said solid [component] additive to 99:1 of said matrix, the mean weight diameter of the particles of said structured system ranging from 25 to 1500 microns and the system displaying a loose bulk density of 0.1 to 1.1 Kg/l.

13. (Twice Amended) The structured particulate system of claim 12 wherein the [nutritionally] active, organic solid [component] additive is selected from the group consisting of oleanoic acid, ursolic acid, folic acid, policosanol and phytosterols.

18. (Amended) The structured particulate system of claim 12 or 13 wherein the weight ratio between active [component] additive and matrix ranges from 80:20 to 20:80.

19. (Amended) The structured particulate system of claim 12 or 13 wherein the weight ratio between active [component] additive and matrix ranges from 60:40 to 40:60.

20. (Twice Amended) The structured particulate system of claim 12 or 13 wherein the [nutritionally] active, organic solid [component] additive has a discrete particle size within the total structured particulate system of 2 to 275 microns.

21. (Twice Amended) The structured particulate system of claim 12 or 13 wherein the [nutritionally] active, organic solid [component] additive has a discrete particle size within the total structured particulate system of 5 to 250 microns.

22. (Twice Amended) The structured particulate system of claim 12 or 13 wherein the [nutritionally] active, organic solid [component] additive has a discrete particle size within the total structured particulate system of 7 to 200 microns.

24. (Twice Amended) The structured particulate system of claim 12 wherein the [nutritionally active component] additive is a component that improves the oral properties of a food product, or the system improves the dispersability of the [active component] additive in a food.

26. (Twice Amended) Method for improving at least one property selected from the oral properties of a food product and the homogeneity of an organic solid [nutritionally] active component in a food product, which comprises incorporating in the food product an effective amount of the structured particulate system of claim 12 or 13.

27. (Twice Amended) Method for improving at least one property selected from the oral properties of a food product and the homogeneity of an organic solid

[nutritionally] active component in a food product, which comprises incorporating in the food product from 0.01 to 50 wt %, based on the food product of the structured particulate system of claim 12 or 13.

28. (Twice Amended) Method for improving at least one property selected from the oral properties of a food product and the homogeneity of an organic solid [nutritionally] active component in a food product, which comprises incorporating in the food product from 1 to 30 wt %, based on the food product of the structured particulate system of claim 12 or 13.

30. (Twice Amended) Process for preparing a structured particulate system as defined in claim 12 or 13 which comprises:

(i) mixing a solid organic [nutritionally] active [component] food additive with a matrix into a homogeneous powder;

(ii) adding a solvent to part of the powder obtained to dissolve the matrix resulting in a suspension of the active [component] additive in solvent;

(iii) suspending part of the powder resulting from step (i) in an expansion chamber of a fluid bed; and

(iv) spraying the suspension resulting from (ii) onto the suspended powder of step (iii) in the expansion chamber and drying rapidly by a heating medium.

Example III

Procedure for making structured particulate Apple extract containing 30% ursolic acid on a fluid bed.

Formula mentioned in Table II for an Apple extract content of respectively 25% in the structured particulate added Polyglycerol Esters (Santone 8-1-0) as part of the binder in the spray solution.

Table II

Ingredients	Formula 25%	
Product Bowl		
6X Powder Sugar	50%	1.5kg
Apple extract	26.5%	0.795kg
Dextrose	20.5%	0.616kg
Microcrystalline Cellulose	0.6%	0.018kg
Spray Solution		
Maltodextrin M-100	0.6%	0.018kg
Dextrose	0.6%	0.018kg
Polyglycerol Esters (Santone 8-1-0)	1.2%	0.035kg
Water	0.7kg	

Process:

A. 6X Powder Sugar, Apple extract, Dextrose, and Microcrystalline cellulose are placed in a product bowl on the fluid bed.

B. The equipment used for this example was a pilot-scale 5-kg fluid-bed drier top spray.

C. The maltodextrine, remaining dextrose and polyglycerol esters (Santone 8-1-0) and were mixed in warm water at 50°C as the spray solution.

An initial product temperature range of about 50-55°C was used and an air volume, sufficient (damper 1/2 open) to fluidize the product was set. The spray solution was sprayed onto the product in the bowl at a spray rate of 60 grams per minute with an atomization air pressure of 3.75 bar. The spray rate was increased to 80 grams per minute when 200 grams of solution was remaining. Upon completion of the spray solution, the structured particulate was dried at an outlet air temperature of 50°C for 10 minutes. The structured particulate was measured for loss on drying using a Metler LP-16 Metler Moisture Balance result was 2.6%. The material was sized on a US#16 mesh using a Sweco Sifter to remove any oversized material. The analytical data for Example I (25% Apple extract) are shown in Table II. The methods used for analyzing the structured particulate can be found in USP XXIII/NF19.

Table II

Analytical Data

	Apple extract 25%
PS on #16	0.0%
20	10.1%
60	57.7%
200	25.8%
PAN	6.4%
Loose Bulk	0.39g/cc
Loss on Drying	2.5%
Mean weight diameter	252 microns

The supplier's data for the active component (raw material calcium citrate) indicates that the material has a mean weight diameter of less than 17 microns.

Example IV - Homogeneity

Comparative homogeneity test of structured particulate Apple extract and with non-structured active particulate component:

1. 1 gram of non-structured active particulate component Apple extract is added to 100 ml of 70°C water and 4 grams of structured particulate (Apple extract 25%) to another 100 ml of water.

2. Each sample was mixed for 5 minutes with continuous visual inspection for homogeneity.

It is demonstrated that structured particulate Apple extract 25% disperses readily in water resulting in a homogeneous distribution of Apple extract 25% in the water with accurate dosing. This is in contrast to non-structured active particulate component

Apple extract that clumped together and sticks to the container walls, making it extremely difficult to deliver an accurate dose of Apple extract to the water.

Example V - Flowability

Comparative flow properties test of structured particulate Apple extract and with non-structured active particulate component:

1. 100 grams of non-structured active particulate component Apple extract is added to 60 degree powder funnel, 80mm ID, not allowing any material to pass through and 100 grams of structured particulate (Apple extract 25%) to another 60 degree powder funnel, 80mm ID, not allowing any material to pass through.

2. The caps were removed from the funnels allowing each sample to pour out. The structured particulate (Apple extract 25%) funnel emptied in 4 second were as the non-structured particulate component Apple extract required vibration to allow the material to pass through the funnel.

It is demonstrated that structured particulate Apple extract 25% disperses readily with improved flow properties which allows for accurate dosing. This is in contrast to non-structured active particulate component Apple extract that clumped and sticks in the funnel making it extremely difficult to deliver an accurate dose of Apple extract.

Soy protein isolates, nutritionally active component.

Example VI

Procedure for making structured particulate Soy Protein Isolates ML-70 on a fluid bed.

Formulas are mentioned in Table I for a Soy Protein Isolates content of respectively 70% in the structured particulate.

Table I

Ingredients	Formula 70%	
Product Bowl		
Soy Protein Isolates	70%	2.1kg
Maltodextrin M-100	20.0%	0.6kg
Spray Solution		
Maltodextrin M-100	10.0%	0.3kg
Water	0.800kg	

Process:

A. For this recipe in Table I, Soy Protein Isolates, Maltodextrin M-100 are placed in a product bowl on the fluid bed.

B. The equipment used for this example was a pilot-scale 5-kg fluid-bed drier top spray.

C. The maltodextrin was mixed in warm water at 25°C (15.0% solids in solution) as the spray solution.

An outlet temperature range of about 30-35°C was sued and an air volume, sufficient (damper 1/2 open) to fluidize the product was set. The spray solution was sprayed onto the product in the bowl at a spray rate of 30 grams per minute with an atomization air pressure of 60 psi. Upon completion of the spray solution, the structured particulate was dried at an outlet air temperature of 40°C for 5 minutes. The structured particulate was measured for loss on drying using a Metler LP-16 Metler Moisture Balance result was 4.5%. The structured particulate was sized on a US#10 mesh using a Sweco Sifter to remove any oversized material. Further analytical data for Examples I

is shown in Table II. The methods used for analyzing the structured particulate can be found in USP XXIII/NF19.

Table II

Analytical Data

	Soy Protein Isolates ML-70
PS on #20	4.9%
40	21.7%
60	37.0%
80	19.5%
100	5.5%
200	9.6%
PAN	1.8%
Loose Bulk	0.31g/cc
Loss on Drying	4.5%
Mean weight diameter	277.8 microns

The active component (raw material soy protein isolates) used has a particle size distribution of 90% through a US#100 mesh and loose bulk density of 0.39g/cc. Supplier data indicated that this material had a mean weight diameter of less than 113 microns. The method for analyzing the material can be found in USP XXIII/NF19.

The mean weight diameters were calculated as follows: weight fraction at screen multiplied by screen opening (microns), summed for all screen sizes.

The mean weight diameters were calculated as follows: weight fraction at screen multiplied by screen opening (microns), summed for all screen sizes.

Example VII - Homogeneity

Comparative homogeneity test of structured particulate soy protein isolates with non-structured active particulate component:

1. 20 grams of non-structured active particulate component soy protein isolates is added to 1 kg of vegetable oil and 26 grams of structured particulate (soy protein isolates 70%) to another 1 kg of vegetable oil.

Each sample was mixed for 5 minutes with continuous visual inspection for homogeneity.

It is demonstrated that structured particulate soy protein isolates disperses readily in food products resulting in a homogeneous distribution of soy protein isolates in the products with accurate dosing. This is in contrast to non-structured active particulate component soy protein isolates that clumped together and sticks to the container walls, making it extremely difficult to deliver an accurate dose of soy protein isolates to the food product.

Example VIII - Homogeneity of structured particulates in food

This example illustrates the effect of different forms of isolated soy protein on homogeneity in food products using the structured particulates and soy protein isolates raw ingredient.

Incorporation of Structured Particulate:

Tempered Chocolate. White chocolate (400 g) was weighed out and melted in a bowl. 100 g of Structured Particulate was added to the chocolate and stirred by hand for 20 seconds showing homogeneity. The Structured Particulate mixed very easily into the chocolate. The chocolate mixture was poured into molds, tapped and scraped evenly. The molds were then placed into the cooling chamber at 14.4°C for proper cooling until the chocolate was set. The molds were then removed from the cooling chamber and the chocolates were removed from the molds.

Incorporation of soy protein isolates raw ingredient:

Tempered Chocolate. White chocolate (430 g) was weighed out and melted in a bowl. 70g of soy protein isolates raw ingredient was added to the chocolate and stirred for 20 seconds. The soy protein isolates was very lumpy and difficult to mix therefore the mixing was continued for another 3 minutes. The chocolate mixture was poured into molds, tapped and scraped evenly. The molds were placed into the cooling chamber at 14.4°C for proper cooling until the chocolate was set. The molds were then removed from the cooling chamber and the chocolates were removed from the molds.

Inspection:

The structured particulates and the soy protein isolates raw ingredient white chocolate bars were broken into several pieces. Upon examination, the soy protein isolates raw ingredient white chocolate bars were found to have large tan to off white powdery inclusions, indicating poor homogeneity of soy protein isolates within the chocolate bar. On the other hand, the structured particulate white chocolate bars were found to be free from powdery inclusions and were completely homogeneous.